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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,156	10/11/2005	Andreas Meinke	05-747	4561

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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER

BASKAR, PADMAVATHI

ART UNIT PAPER NUMBER

1645

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/552,156

Applicant(s)

MEINKE ET AL.

Examiner

Padmavathi v. Baskar

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-68 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 38-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Application/Control Number: 10/552,156

Page 2

Art Unit: 1845

RESTRICTION

1 Applicants amendment filed on 3/31/06 has been entered.

Claims 1-37 have been canceled.

Claims 38-68 have been entered and are pending in the application.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 38 -47 and 48 drawn to *Streptococcus pneumoniae* antigen and a pharmaceutical composition.

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

Group II, Claims 49-52, 54 and 53 , drawn to antibody to *Streptococcus pneumoniae* antigen, a pharmaceutical composition and a method of producing antibody respectively.

Group III, Claims 55 , 56 and 66, drawn to a method of diagnosing *Streptococcus pneumoniae* infection using antibody.

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

Group IV, Claims 57-58 and 66 drawn to a method of treating *Streptococcus pneumoniae* infection using antibody.

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

Group V, Claims 59-60 and 66 drawn to a method of immunizing an animal against *Streptococcus pneumoniae* infection using polypeptide.

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

Application/Control Number: 10/552,156

Page 3

Art Unit: 1645

Group VI, Claims 61-65 and 66 drawn to a method of stimulating an immune response in an animal against *Streptococcus pneumoniae* infection using antigen.

Group VII, Claims 67 and 68 drawn to a method of diagnosing *Streptococcus pneumoniae* infection using antigen.

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

3. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special feature technical features for the following reasons:

The technical feature of linking groups appears to be that they are all related to hyper *S. pneumoniae* immune serum reactive antigens.

However, Mc Cool (J Exp Med. 2002 Feb 4;195(3):359-65) disclose 22 kD protein antigen identified it as the NH(2)-terminal region of pneumococcal surface protein A (PspA) reactive to serum IgG and secretory IgA (see abstract and figures 1-4) . Therefore, the technical feature of linking groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

The special technical feature of Group I is considered to be antigen , made up of amino acids.

The special technical feature of Group II considered to be antibody that shares no common structure, property and function from Invention I since it has an inherent affinity, avidity, and specificity that a simple protein is not capable of expressing and do not require each other for their practice.

Application/Control Number: 10/552,156

Page 4

Art Unit: 1645

Since the special technical feature of the Group I invention is not present in the Group II claims, and the special technical features of the Group II inventions are not present in the Group I claims, unity of invention is lacking.

The technical feature linking Groups III-VII is considered to be methods utilizing products that share no common structure, property, function and lack the same or a corresponding special technical feature so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among groups III-VII.

Accordingly, Groups I-VII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

DISTINCT INVENTIONS

4. For each group of inventions I-VII above, restriction to one of the following SEQ.ID.NO is also required under 35 U.S.C. 121 and 372. Therefore, election is required of one of inventions I-VII and one of SEQ ID NO: 214 or 243.

Invention SEQ ID NO: 214 and SEQ ID NO: 243 are not so linked as to under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claimed antigens SEQ.ID.NO: 214 and SEQ ID NO: 243 share no common special technical feature because the antigens have no common structure (i.e., no common sequence) and are not linked by the same the same or a corresponding special technical feature as to form a single general inventive concept. Therefore, where structural identity is required, such as expression of protein or binding of antibody, each sequence appears to be structurally different and induce a specific immune response. Thus they share no common structure and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among SEQ.ID.NO :214 and 243.

Application/Control Number: 10/552,156

Page 5

Art Unit: 1645

Applicant is required under Restriction is required under 35 U.S.C. 121 and 372 to elect a single disclosed SEQ.ID.NO from any group elected.

5. This application contains claims 46 and 64 directed to the following patentably distinct species: immunostimulatory substance is a polycationic polymer, an immunostimulatory deoxynucleotide (ODM), a peptide containing at least two Lys-Leu-Lys motifs, a neuroactive compound, alum, or a Freund's complete or incomplete adjuvant. The species are independent or distinct because each immunostimulatory molecule is structurally and functionally are different and distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is required in reply to this action to elect a group, one sequence SEQ.ID.NO and one immunostimulatory substance and identify to which the claims shall be restricted. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

6. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

TO: PADMA BASKAR COMPANY:

Application/Control Number: 10/552,158

Page 6

Art Unit: 1645

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0884. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

